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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/466,921	06/06/95	ALIZON	M 03459.0008-0

HM21/0316
FINNEGAN HENDERSON FARABOW
GARRETT AND DUNNER
1300 I STREET NW
WASHINGTON DC 20005-3315

EXAMINER
PARKIN, J

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/16/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/466,921

Applicant(s)
Alizon et al.

Examiner
Jeffrey S. Parkin, Ph.D.

Group Art Unit
1648



☒ Responsive to communication(s) filed on 15 Dec 1997

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 28, 29, and 32-45 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 39-45 is/are allowed.

☒ Claim(s) 28, 29, and 32-38 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to Amendment

Status of the Claims

1. Acknowledgement is hereby made of Applicants' response filed 15 December, 1997. Claims 28, 29, and 32-45 are pending in the application.

35 U.S.C. § 112, First Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The previous rejection of claims 39-45 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is hereby withdrawn in response to the Declaration of Mme. Danielle Berneman.

4. Claims 28, 29, and 32-38 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claimed invention is directed toward HIV-1 DNA restriction fragments. The disclosure provides preliminary restriction maps of LAV cDNA (e.g., pLAV75, pLAV82 and pLAV13) and lambda phage clones (e.g., λJ19 and λJ81) (refer to Figures 1 and 2). The restriction coordinates are disclosed on page 4, as well as a series of restriction fragments

believed to correspond to the *gag*, *pol* and *env* coding regions (e.g.,
*Pst*I (800 nt)/*Kpn*I (3500 nt); *Kpn*I(3,500 nt)/*Bgl*II (6,500 nt); *Kpn*I
(6,100)/*Bgl*II (9150)). The specification does not disclose, *ipsis*
verbis, HIV/LAV viral clones or restriction fragments obtained from
any other viral isolate.

Applicants traverse and assert that the teachings of Goodenow *et*
al. (1989), Holland *et al.* (1992), and Gao *et al.* (1994) were
improperly relied upon because they were published after applicants'
filing date. Applicants further argue that the disclosure clearly
teaches the skilled artisan to determine whether or not they possess
the claimed invention. Applicants arguments have been thoroughly
considered but are not deemed to be persuasive for the reasons of
record in paper no. 15 and as further elaborated below.

Concerning the first aspect of applicants' traversal, although it
is generally preferred that the submission of pre-filing date, or
effective filing date, references should be provided to support a
prima facie demonstration of lack of enablement, nonetheless, it is
also acceptable to submit later-dated references if they provide
evidence as to what was known on or before the effective filing date
of the application. Thus, if individuals skilled in the art state
that a particular invention is not feasible after the filing date of
the claimed invention, that would be sufficient evidence that the
invention was not possible at the time of filing. Moreover, the
court decided in *In re Budnick*, 190 U.S.P.Q. 422 (C.C.P.A. 1976),
that the argument of counsel cannot take the place of evidence. The
references relied upon were cited only to demonstrate that HIV-1
exists as a complex group of genotypic and phenotypic variants. Each
variant will have a unique nucleotide sequence and varying
restriction endonuclease profiles.

Concerning the second aspect of applicants' traversal and contrary
to the arguments presented, the disclosure fails to adequately teach

the skilled artisan how to arrive at the instant invention. The claims simply recite a purified HIV-1 restriction fragment. At the effective filing date of the applicants' invention, detailed nucleotide sequence listings and restriction maps were not available. Considering the quasispecies nature of lentiviruses, the skilled artisan, *a priori*, could reasonably assume that variants exist containing nucleotide sequence additions, deletions, and various substitutions. Accordingly, it is not readily manifest how the skilled artisan could make or determine if they were in possession of the claimed invention absent further limitations in the claim language (i.e., a purified HIV-1 DNA fragment generated by a *Bam*HI site at approximately 8150 and a *Bgl*III site at approximately 9150 wherein said fragment is capable of hybridizing to the corresponding λ J19 restriction fragment under conditions of . . .). Therefore, the rejection is maintained.

35 U.S.C. § 112, Second Paragraph

5. Claims 28, 29, and 32-38 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

Applicants traverse, citing *in re Morosi* and *in re Wilson*, and assert that the precise location of the claimed restriction sites is not required. Applicants' arguments have been thoroughly considered but are not deemed to be persuasive for the reasons of record in paper no. 15. As previously set forth, the claim language fails to clearly and distinctly set forth the subject matter being claimed. Accordingly, the metes and bounds of the patent protection desired

cannot be ascertained.

Allowable Subject Matter

6. Claims 39-45 appear to be free of the prior art and are allowable.
5 Claims 28 and 29 would also be allowable with appropriate amendment
of the claim language to reflect their dependence upon claims 39-45.

Finality of Office Action

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension
10 of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS
SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE
EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE
OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL
15 AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE
SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY
ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R.
§ 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY
ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE
20 LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

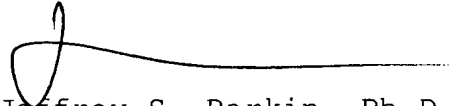
8. The Art Unit location of your application in the Patent and
25 Trademark Office has changed. To facilitate the correlation of
related papers and documents for this application, all future
correspondence should be directed to **art unit 1648**.

9. Correspondence related to this application may be submitted to
30 Group 1600 by facsimile transmission. The faxing of such papers must
conform with the notice published in the Official Gazette, 1096 OG 30
(November 15, 1989). Official communications should be directed
toward one of the following Group 1600 fax numbers: (703) 308-4242 or
(703) 305-3014. Informal communications may be submitted directly to
35 the Examiner through the following fax number: (703) 305-7401.
Applicants are encouraged to notify the Examiner prior to the

submission of such documents to facilitate their expeditious processing and entry.

5 10. Any inquiry concerning this communication should be directed to
Jeffrey S. Parkin, Ph.D., whose telephone number is **(703) 308-2227**.
The examiner can normally be reached Monday through Thursday from
8:30 AM to 6:00 PM. A message may be left on the examiner's voice
mail service. If attempts to reach the examiner are unsuccessful,
the examiner's supervisor, **Donald E. Adams, Ph.D.**, can be reached at
10 **(703) 308-0570**. Any inquiry of a general nature or relating to the
status of this application should be directed to the Group 1600
receptionist whose telephone number is (703) 308-0196.

Respectfully,


Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 31648

12 March, 1998


LAURIE SCHEINER
PRIMARY EXAMINER